Welcome to our annual report 2018

The European Clinical Research Infrastructure Network (ECRIN) is a sustainable, non-profit, distributed infrastructure with the legal status of a European Research Infrastructure Consortium (ERIC).

ECRIN supports multinational clinical trials in Europe, which provide increased access to patients, resources and expertise. In particular, ECRIN supports investigators and sponsors in the planning and design of clinical trials, and can subsequently provide services for the management of multinational trials. ECRIN is also involved in activities to enhance the ability of European sponsors to successfully conduct multi-country clinical research (e.g. tools/database development, data centre certification). Moreover, ECRIN is involved in infrastructure development projects that aim to further develop the European clinical research community and facilitate multinational trials.

ECRIN has nine member countries (Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Portugal and Spain) and two observer countries (Switzerland and Slovakia).

European Clinical Research Infrastructure Network
5 rue Watt - 75013 Paris
France
Dear reader,

We are proud to present ECRIN’s Annual Report for 2018. This year was particularly significant in that it marked the fifth year of operation since ECRIN was awarded the legal status of a European Research Infrastructure Consortium (ERIC).

Other highlights for 2018 included the addition of a new member country (Ireland) and a new observer country (Slovakia), while Czech Republic went from being an observer to a full-fledged member. This brought our total number of member countries to nine and observer countries to two.

Throughout 2018, we continued to expand our clinical trial portfolio and supported the management of multinational, academic clinical trials covering diverse medical fields and diseases. We also continued to work on infrastructure development projects that aim to further develop the European clinical research community and facilitate multinational trials.

We are proud of what we have accomplished with our many European and international partners so far, and are excited to continue striving to achieve our vision: the generation of scientific evidence through multinational clinical trials to enhance medical practice, and ultimately, to improve public health.

Our main priorities moving forward are the optimisation of our human and financial resources to continually improve our ability to provide the highest quality support services. This report provides an overview of how we used these resources in 2018 to achieve our goals.

We look forward to facilitating multinational clinical trials in collaboration with our outstanding partners in Europe and internationally. Together, we hope to make even greater progress towards more evidence-based medical decisions. We thank you for your interest and continued support.

Sincerely,

Jacques Demotes
Director General of ECRIN
Foreword from the Chair and Vice-Chair of the Assembly of Members

[Infrastructure development projects] are a great opportunity to collectively address clinical research issues, and to identify and develop the tools and services needed to enhance the European clinical research landscape for all.

Dear reader,

2018 was another busy year for ECRIN. The organisation continued to strive to achieve the goals set out in the 2016-2019 strategy plan, and to optimise its governance to meet the demands of an increasing number of member and observer countries. Five years after having taken off, it was decided to carry out a truly external, independent assessment in 2019 as part of the policy of transparency and ‘good value for money’.

ECRIN’s raison d’être remains the provision of high-quality support services to its participating countries, helping its national scientific partners to connect to partners in other ECRIN member and observer countries, as well as to partners elsewhere in Europe and beyond. This type of cross-border collaboration is of great value to individual countries and to Europe as a whole. Multinational clinical trials mean greater access to patients, expertise, resources, and more, which in turn means faster and more robust results. For individual European countries, this is a huge advantage.

With ECRIN’s support, countries can gain easier access to other national networks (composed of clinical trial and/or clinical research units), research communities, and facilities. Collectively, they can develop and implement innovative research projects to tackle the pressing questions that might otherwise go unaddressed in clinical studies involving paediatric patients (now 20% of ECRIN’s portfolio) or adult patients – and which may have a potentially great impact on public health.

A particular benefit for researchers is access to the hundreds of millions of European inhabitants and potential patients. This is especially relevant for rare diseases, whereby a single country may only have a handful of cases, making a clinical trial extremely difficult (or slow) to conduct.

ECRIN is an active actor in promoting collaboration with other research infrastructures (RIs) in the biological and medical sciences area (both those in the preparatory phase and those which are already ESFRI’s ‘Landmarks’), as well as with other European RI consortia (ERIC Forum). Of note, ECRIN has signed a long-term cooperation agreement with the BBMRI and EATRIS ERICs, and is actively involved in the European Joint Programme on Rare Diseases (EJP RD).

Beyond multinational clinical trials (investigating drugs, devices and/or novel study designs/strategies), ECRIN’s member and observer countries are involved in various infrastructure development projects supported by ECRIN. Such initiatives are a great opportunity to collectively address clinical research issues, and to identify and develop the tools and services needed to enhance the European clinical research landscape for all.

Finally, ECRIN supports its member and observer countries to develop their own national infrastructure, as appropriate. In this way, ECRIN plays a dual role: it promotes stronger collaboration between countries, and supports infrastructure development within individual countries.

ECRIN’s solid growth in 2018 in terms of number of trials, projects and member/observer countries once again highlights the underlying strength of this unique organisation. We believe that ECRIN has the potential to achieve even more by attracting additional member and observer countries. Because, more countries means more potential for multi-country collaboration, and when it comes to clinical trials and research, the more the better.

Sincerely,

Maria Ferrantini
Vice chair of ECRIN’s Assembly of Members (Istituto Superiore di Sanità, ISS – Italy)

Rafael de Andrés
Chair of ECRIN’s Assembly of Members (Instituto de Salud Carlos III, ISCIII – Spain)

1 European Strategy Forum on Research Infrastructures (ESFRI)
Mission, Vision and Focus Areas

ECRIN MISSION
To support the conduct of multinational clinical research in Europe

ECRIN VISION
To generate scientific evidence to optimise medical practice

Focus Areas Moving Forward
✓ Increasing the number of ECRIN-supported trials.
✓ Expanding the number of member / observer countries.
✓ Promoting quality inside the organisation.
✓ Further developing partnerships.
✓ Increasing our involvement in strategic / science policy actions.
✓ Developing tools / services adapted to the clinical research context.

2018 in Numbers

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<th>5</th>
<th>9</th>
<th>2</th>
<th>35</th>
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<tr>
<td>Years that ECRIN has had ‘ERIC’ status</td>
<td>Member countries</td>
<td>Observer countries</td>
<td>Number of trials (current) supported by ECRIN</td>
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<th>9</th>
<th>6</th>
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<tr>
<td>New infrastructure development projects funded</td>
<td>Average number of countries per ECRIN-supported trial</td>
<td>Data centres certified since 2014</td>
<td>Total ECRIN budget</td>
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6
Number of scientific articles (co)authored by ECRIN and published

500
Twitter followers

18,941
Website visitors

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2 Focus areas are adapted from those proposed in the work plan developed at the end of 2018, and are applicable for 2019 (and beyond).

3 ECRAD-Plan, EJP-RD, EOSC-Life, ERIC Forum, EuLac-PerMed, Ri-VIS, SYNCHROS, EBRA, TBMed. For full names and funding information, see the ‘Infrastructure Development’ section below.

4 Data derived from Google Analytics for the period from 1 January 2018 to 31 December 2018.

5 Ibid.
Celebrating 5 Years as an ERIC

2018 marked the fifth anniversary since ECRIN was awarded the status of a European Research Infrastructure Consortium (ERIC) by the European Commission6.

ECRIN began in 2004 and matured through European Union (EU) Framework Programme 6 (FP6) and FP7 funding. In 2006, it was listed on the European Strategy Forum on Research Infrastructures (ESFRI) roadmap. In those first years it focused on developing its strategy, tools, and infrastructure to achieve its goal: supporting European sponsors and investigators to overcome the barriers to multinational clinical research.

The awarding of ERIC status in November 2013 was a key development, as it ensured ECRIN’s financial sustainability by enabling the organisation to receive financial contributions from its member and observer countries.

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6 The ERIC legal status is recognised in all EU member states, and is designed to facilitate the establishment and operation of research infrastructures (RIs) of European interest.
### 2018 Highlights

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<th>Jan</th>
<th>Mar</th>
<th>May</th>
<th>Jul</th>
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<tr>
<td>• Czech Republic became a member (1 Jan.)</td>
<td>• 1st Clinical Research Initiative for Global Health (CRIGH) General Assembly in Tokyo (7-8 Mar.)</td>
<td>• International Clinical Trials Day (ICTD) meeting in Budapest (15 May)</td>
<td>• Slovakia became an observer (1 Jul.)</td>
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<td>• European correspondent (EuCo) face-to-face meeting (24-25 Jan.)</td>
<td>• EuCo face-to-face meeting (21-22 Mar.)</td>
<td>• Assembly of Members (AoM) meeting (15 May)</td>
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<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
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<td>• Audited 2 data centres in Japan and trained 3 auditors (pilot for globalisation of the data management centre certification programme)</td>
<td>• Organised the 3rd annual CORBEL Medical Infrastructure/Users Forum (MIUF) ii meeting in Paris (15 Oct.)</td>
<td>• Ireland became a member (20 Nov.)</td>
<td>• Finalised 2019 work plan</td>
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<td>• Summer School meeting in Toulouse (3-5 Sept.)</td>
<td>• Certified 3 new data centres in Europe: KKS Dresden (Coordination Centre for Clinical Trials Dresden); Coordination Centre for Clinical Trials (KKS) Heidelberg; Ospedale Pediatrico Bambino Gesu (OPBG), Rome.</td>
<td>• Ritrain staff exchange for RI managers (22-23 Nov.)</td>
<td>• Assembly of Members (AoM) meeting (11 Dec.)</td>
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<td>• Czech Republic became an observer (1 Jul.)</td>
<td>• Summer School meeting (3-5 Sept.)</td>
<td>• Launch of the ECRIN pharmacovigilance qualification project for developing harmonised standards of reference</td>
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<tr>
<td>• Slovakia became an observer (1 Jul.)</td>
<td>• Organised the 3rd annual CORBEL Medical Infrastructure/Users Forum (MIUF) ii meeting in Paris (15 Oct.)</td>
<td>• Launch of the ECRIN quality group aiming to promote quality across national hubs</td>
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What We Do

ECRIN is a sustainable, non-profit, distributed infrastructure that strives to overcome the obstacles to multinational trials in Europe.

In particular, ECRIN supports investigators and sponsors in the preparation of trial protocols and funding applications, and can subsequently provide services for the management of multinational trials. It focuses on independent, multinational academic research as well as trials initiated by biotech and medical device small and medium-sized enterprises (SMEs).

ECRIN is also involved in activities to enhance the ability of European institutions to successfully conduct multi-country clinical research (e.g., tools/database development, data centre certification). Moreover, ECRIN participates in infrastructure development projects. Updates on ECRIN’s trial support and project activities in 2018 can be found below.

How ECRIN works with national partners

Organisation

ECRIN’s organisational model is based on country membership. In 2018, it had nine member countries (Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Portugal and Spain) and two observer countries (Slovakia and Switzerland).

Each country hosts a European correspondent (EuCo) who is seconded to ECRIN by the national scientific partner, that is, a network of academic clinical trial units (CTUs) and/or clinical research centres (CRCs) located at or affiliated to national universities and hospitals. EuCos are clinical research experts with extensive knowledge of the national and European clinical research landscape; they manage the clinical trial portfolio and coordinate with the national scientific partner with support from the Paris-based core team.

Funding

ECRIN is funded by the contributions of its member and observer countries. These funds are primarily dedicated to supporting the organisation and developing its core competencies. In addition, ECRIN receives funds from European funding bodies (e.g., Horizon 2020) that cover specific activities carried out as part of multinational clinical trials or infrastructure development projects.

Financial contributions were received from member countries in 2018. Observer countries paid for the cost of their respective local EuCos. Following the addition of new member / observer countries, the consolidated ECRIN statutes and the Annex II of the ECRIN statutes (list of members and observers) were updated in December 2018.

1 Documents available here: www.ecrin.org/who-we-are/organisation-funding
Clinical Trial Operations

ECRIN’s Support in a Changing Research Landscape

In 2018, ECRIN’s clinical trial activities continued to reflect significant changes in the clinical research landscape and funding policy/ecosystem, one of which is the rise of personalised medicine. In particular, ECRIN supported a significant number of applications for European funding (H2020) for multinational studies on patient stratification (as part of personalised medicine programmes). As such, ECRIN extended its traditional support for randomised clinical drug trials to support for new clinical research areas and methodologies (e.g. the identification of biomarkers, prospective cohorts and medical device investigations).

The sections below provide a closer look at the type of support ECRIN provides from preparation to implementation, and highlights the number of applications that ECRIN supported in 2018. The ECRIN clinical trial portfolio (ongoing trials as of 2018) is also presented.

Overview

ECRIN’s core activity is clinical trial operations, which was naturally its focus in 2018. ECRIN provides support to investigators and sponsors in ECRIN member and observer countries for the preparation of European funding applications and the validation of study protocols. Provided that projects meet ECRIN’s eligibility criteria, ECRIN can also provide various trial management services to sponsors / project coordinators. As part of its operations activities, ECRIN also contributes to the development of tools designed to facilitate multinational clinical research.

Personalised Medicine

Personalised medicine aims to deliver the best and most appropriate healthcare strategy to each patient subgroup. This requires the identification of patient groups based on the understanding of disease mechanisms (hypothesis-driven approach) or following mechanism-agnostic clustering (data-driven approach). Although both approaches can co-exist, the data-driven approach is now made easier because of the availability of large multimodal datasets combining clinical, imaging and multiomics data from broad patient populations, collected either prospectively or retrospectively in the context of observational or interventional studies. Such large datasets are exploited by machine-learning algorithms to stratify the patient population.

Regardless of the approach used to stratify patients, randomised clinical trials are necessary to compare and validate treatment strategies. Depending on the nature of the biomarker signature underpinning stratification, and the understanding of the drug’s mechanism of action, linking a biomarker profile with a treatment option may be a relatively easy or very difficult task. New designs (i.e. basket and umbrella trials) are becoming more widespread in randomised trials in order to validate proposed treatment options. Moreover, ‘platform trials’, which entail continuous, multi-arm testing of multiple drugs for a given disease condition, are becoming increasingly prevalent. Although these approaches were first designed and implemented in the field of cancer, they have now spread rapidly to other disease areas.
Clinical Trial Operations - ECRIN Annual Report 2018

Clinical Trial Portfolio in 2018 (current trials)

In 2018, ECRIN’s trial portfolio included 35 ‘current’ trials (this includes trials that started before or during the year, as well as trials that were funded in 2018 with a start date in 2019). The trial portfolio above illustrates the country coordination / participation for ECRIN-supported trials as of 31 December 2018.

Clinical Trial Portfolio (all trials)

The total ECRIN trial portfolio, including past studies, reached 58 studies in 2018. The illustrations on the next page all include data for both current and past studies.

Grant Application Support

In the planning phase, ECRIN can give input on the different aspects of funding applications such as work package architecture, potential impact, management, governance, consortium composition, and multinational clinical trial management. ECRIN can also advise on the types of available (European) funding and how to go about applying.

EuCos, who act as the intermediary between the sponsor and service providers (i.e., national networks and CTUs), can provide information in particular on the facilities that have the capacity and services needed to manage the trial. They ensure that the CTUs selected for the study are an appropriate fit, both in their country and in other European countries. They can also advise on anything from ethical/regulatory requirements to trial insurance, and can provide a logistical evaluation and/or risk assessment (see below) of project plans.

In 2018, ECRIN proposed comprehensive support to investigators and sponsors for funding applications. While the majority of support was provided for H2020 calls, ECRIN also assisted with applications to projects such as conect4children (c4c) (funded by the Innovative Medicines Initiative, IMI). It was also contacted directly by other (academic) funders and various industry groups to participate in calls/trials.

In 2018, ECRIN was involved in nine clinical trial proposals (for H2020/IMI funding), which include a mix of stage-1 and stage-2 calls. One proposal was accepted (funded), one was placed on the reserve list, two were accepted for stage-2, and five were rejected.

Collaboration Committee

ECRIN has an internal Collaboration Committee which meets once weekly to discuss whether or not to move forward with proposals. The goal is to make an early, transparent decision on the support to be provided to funding applications based on a project synopsis and task requirements. In 2018, the Collaboration Committee reviewed 38 proposals, and agreed to collaborate on 21 of them.

Risk Assessment

Once funding has been secured, and before implementation, projects can be submitted to ECRIN for risk assessment. EuCos can assess the risk related to project implementation (e.g. patient recruitment, timelines, budget). They can also give suggestions and alternatives to minimise any identified risk factors. Moreover, ECRIN can provide peer-review of the pre-final protocol to avoid risk of bias, with recommendations on how to reduce this risk. This review is done by ECRIN’s Scientific Board of clinical research and methodology experts.

Trial Management Support

During project implementation, ECRIN delivers various trial management services to sponsors / project coordinators. ECRIN coordinates these services, some of which are performed directly by CTUs in ECRIN’s member and observer countries.

In particular, ECRIN can provide support for:

- Project management (central and local)
- Submissions to regulatory authorities and ethics committees
- Monitoring (on-site or remote)
- Local and central pharmacovigilance tasks and adverse event reporting
- Central data management (through ECRIN’s certified data centres)
- Bio-banking
- Selection and provision of qualified resources, and other tasks

In addition, various existing projects contacted ECRIN throughout the year to see if the organisation could provide trial management support services.
Support to investigators and sponsors for funding applications

Countries in ECRIN-Supported Trials
Infrastructure Development

In addition to supporting trials, ECRIN is an active player in European infrastructure development projects. These projects may involve other European RIs working across a wide range of areas and offering diverse services. The goal of these partnerships is to link RIs to develop tools, services, training, landscape analysis, and/or resources, as well as to increase the visibility of the RIs. Other infrastructure development projects aim to develop and upgrade ECRIN’s capacity, tools and services.

In 2018 ECRIN continued to be involved, as coordinator or participant, in various H2020 projects. Updates on select projects and activity areas are provided below.

Ongoing and New Projects in 2018

PedCRIN

In 2018, ECRIN continued to manage the H2020-funded Paediatric Clinical Research Infrastructure Network (PedCRIN) project. Launched in 2017, PedCRIN involves the development and testing of tools and services designed specifically to support paediatric trials. In 2017, there was a call to fund investigator-initiated paediatric or neonatal interventional clinical studies on medicinal products to support study management tasks in countries other than the coordinating country. Three studies were selected from this call: 1) The WE-study–Walking Easier with cerebral palsy, 2) A randomised trial of prophylactic oropharyngeal surfactant for preterm infants: the POPART trial, 3) Oxytocin Treatment in Neonates/Infants with Prader-Willi syndrome: effects. In 2018, PedCRIN began to provide trial management services and tools to these trials.

Learn more: www.pedcrin.org

Other Paediatric Projects

ECRIN’s involvement in PedCRIN reflects the organisation’s greater commitment to clinical research and infrastructure development in the field of paediatrics. This can also be seen through two related projects: the European Paediatric Translational Research Infrastructure (EPTRI) and c4c.

EPTRI aims to propose developmental models for a future translational research infrastructure focused on paediatric medicine development. c4c aims to establish a pan-European network of paediatric hospitals to access and investigate paediatric patients in industry-sponsored and investigator-initiated trials.

The goal of such a network is to avoid duplication in the paediatric research community and to pool resources and competencies. This in turn would help to establish stable partnerships between RIs and scientific communities, as promoted by the Coordinated Research Infrastructures Building Enduring Life-science Services (CORBEL) ‘Medical Infrastructure / Users Forum’ (MIUF, see below). The strengthening of a paediatric network could also benefit the rare disease community, as paediatric projects/trials frequently address rare diseases.

CORBEL

CORBEL is another H2020-funded project that was a focus in 2018. The project aims to establish shared services between the ESFRI Biological and Medical Sciences Research Infrastructures (ESFRI BMS RIs)–which includes ECRIN–for the biomedical research community. This is achieved through the creation of ‘cross-infrastructure scientific workflows’, development of common services (which meet specific user/infrastructure needs), and development of partnerships with user communities. One highlight in 2018 was the third annual general meeting, organised by ECRIN and held in Paris from 16 to 17 October 2018.

Learn more: www.corbel-project.eu
In the context of CORBEL, ECRIN also continued to lead the work package for the MIUF. This is a unique forum that enables dialogue and action planning between various stakeholders involved in European clinical research including medical research communities, funding bodies, and medical RIs. In 2018, a key event was the MIUF’s third annual meeting in Paris on 15 October. The meeting addressed the following topics: the structuring of medical research communities at pan-European level; the needs of medical research projects in the context of big data and personalised / stratified medicine; and data service challenges. In regards to medical community structuring, participants noted challenges related to project sustainability, quality, training, information sharing and strategic vision. As for medical research project needs, speakers shared success stories involving cross-cutting technical expertise to address scientific questions. They also underlined potential challenges, including data collection, anonymisation, clean-up/structuring, storage, sharing, and more. Finally, in terms of data, participants noted in particular that the sharing/reuse of multimodal data, images, and biosamples is essential to optimise the use of research data. It was also noted that policies for data sharing and reuse are generally lacking, hindering the reuse of sensitive data at a larger scale across national borders.

Data Sharing
Data sharing and optimal reuse of data are key challenges for the clinical research community. In 2018, ECRIN continued to address data sharing issues through its involvement in various projects. For example, in the aforementioned CORBEL project, ECRIN works on clinical trial data sharing and reuse, and participates in the development of solutions for multimodal data management.

Projects Funded in 2018
In 2018, multiple new infrastructure development projects involving ECRIN as a partner received positive funding decisions (with kick-offs scheduled for early 2019). These projects are grouped by thematic area below.

PARTNERSHIPS WITH MEDICAL SPECIALITIES
• EBRA (European Brain Research Area x)
• ECRAD-Plan (European Clinical Research Alliance on Infectious Diseases Business Plan xii)
• EJP-RD3 (European Joint Programme on Rare Diseases xii)
• TB Med (A testing bed for the development of high-risk medical devices xii)

DATA
• EOSC-Life (Providing an open collaborative space for digital biology)

Another data-related project is the H2020-funded eXtreme DataCloud (XDC) xvi aimed at developing scalable technologies for federating storage resources and managing data in highly distributed computing environments. The services provided will be capable of operating at the unprecedented scale required by the most demanding, data intensive, research experiments in Europe and worldwide.

A Closer Look at Data Challenges
Multimodal data management and stratification through machine learning are becoming common practice. This raises various challenges, namely the exploitation of multinational datasets (through the development of a system for the sharing/reuse of clinical research data). Issues here include differing data standards and interoperability across countries, or between observational and interventional studies. Personal data protection / data security in the context of the General Data Protection Regulation (GDPR) must also be taken into account. Yet, the ability to reuse data would represent a major breakthrough for clinical research, and even more so if data were to be available for transnational or multinational studies.

x Learn more: www.ecrin.org/news/corbel-miuf-meeting

xii Learn more: www.ecrin.org/activities/
Partnerships

ECRIN highly values its partnerships with its scientific partners in its member and observer countries, as well as with diverse organisations and networks in Europe and beyond.

ECRIN Membership and Collaboration

The expansion of ECRIN membership was a key priority in 2018, and progress was made in attracting new countries. As mentioned above, the Czech Republic changed its status from an observer country to a member country on 1 January 2018. Slovakia became an observer on 1 July 2018, and Ireland became a member on 20 November 2018. Additional countries expressed interest in joining as well and discussions continue with these states.

Following the addition of new member and observer countries, the consolidated ECRIN statutes and the Annex II of the ECRIN statutes (list of members and observers) were updated in December 2018. These documents are available here: www.ecrin.org/who-we-are/organisation-funding

Investigation Networks

Although ECRIN supports trials in any disease area, it values the establishment of partnerships with disease-specific networks. In 2018, ECRIN maintained its relationships with pan-European investigation networks. Links were strengthened in particular with investigator communities on paediatrics and ophthalmology.

Projects to Promote International Partnership and Multinational Collaboration

ECRIN also seeks to facilitate multinational clinical research on a global level through various projects, one example being the Clinical Research Initiative for Global Health (CRIGH), launched in 2017. A follow-up to the Organisation for Economic Co-operation and Development (OECD) Global Science Forum (GSF) initiative 10, CRIGH aims to serve as a support structure for international collaboration on clinical research for the benefit of patients, healthcare professionals, and health systems. The CRIGH secretariat is shared by the US National Institutes of Health (NIH) and ECRIN, and the project brings together research institutions across the globe.

Learn more: www.crigh.org

ECRIN highly values its partnerships with its scientific partners in its member and observer countries, as well as with diverse organisations and networks in Europe and beyond.

Other Partners

ECRIN works with many other partners across the globe. These groups or organisations are typically focused on clinical research in general, or on a specific research area or particular disease. Located in Europe and internationally, they may be directly involved in ECRIN-supported trials or projects, or may also simply wish to maintain close contact with ECRIN and support its goals.

ECRIN’s partners may be designated as affiliate or international partners, depending on the nature of the collaboration and agreement signed (i.e. framework agreement or memorandum of understanding, MoU). Additional partners include data centres that have received ECRIN certification. 2018 was marked by the addition of three new certified data centres (for more information, see the Quality section below).

For the full list of ECRIN-certified data centres and affiliate or international partners, see here: www.ecrin.org/who-we-are/partners

10 An OECD Global Science Forum (GSF) initiative started in 2008 with the aim of fostering international cooperation in non-commercial trials, leading to a report in 2011, followed in 2012 by the ‘OECD Recommendation on the Governance of Clinical Trials’.

For the full list of CRIGH participants, see here: www.crigh.org/members-observers
Quality

This section presents the challenges, opportunities and achievements for quality in 2018.

**ECRIN Internal Quality Management System (QMS)**

Following the decision in early 2017 to apply for ECRIN ISO 9001:2015 certification, ECRIN continued to make the upgrading of its quality management system (QMS) a strategic priority throughout 2018.

ECRIN’s QMS is fit-for-purpose and has been adapted to its distributed infrastructure. It follows a risk and process-based approach, which is founded on the recommendations of the ISO 9001:2015 standard and the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP; document E6(R2))xviii. It aims to coordinate and structure the organisation’s activities to meet customer and regulatory requirements, and to improve effectiveness and efficiency on an ongoing basis.

In 2018, ECRIN continued to adapt to changes in the clinical trial regulatory environment and other requirements such as: the European adoption in June 2017 of the aforementioned ICH E6(R2) GCP Guideline, EU Clinical Trial Regulation 536/2014xix, and the EU General Data Protection Regulation (GDPR) 2016/679x. ECRIN also made significant progress in 2018 in the preparation of its QMS for ISO 9001:2015 certification. In particular, it formalised processes related to competencies and training, risk management, audit and compliance management, as well as continuous improvement management (through Corrective Action and Preventive Action, CAPA). Also in 2018, ECRIN’s information systems were evaluated for sustainability, and began to be optimised to increase efficiency and ensure security compliance with GDPR rules.

ECRIN’s Quality and Risk Councilxii met for its annual meeting to review overall quality performance. In particular, the Council evaluated the pre-defined key performance indicators (KPIs) for ECRIN’s processes, as well as its risk-based internal auditing programme. Recommendations and adjustments were made to improve the overall QMS.

Finally, in order to fulfil its coordination role and the responsibility given to it by the clinical trial sponsor, ECRIN continued to collect information from its partners to ensure that they meet the highest capacity and quality standards. This was achieved through a self-assessment questionnaire, which must be completed before the provision of services begins.

Quality as a Service: Data Management Centre Certification Programme

ECRIN also offers ‘Quality as a Service’ through its Data Management Centre Certification programme. The programme certifies non-commercial data centres from ECRIN member and observer countries which have demonstrated that they can provide safe, secure, compliant and efficient management of clinical research data. Data centres can apply to the programme through an annual call for applications. Applications are assessed by the ECRIN Independent Certification Board (ICB)xiii.

An on-site audit is performed to assess the centre’s data management activities and IT infrastructure. This is done using published ECRIN data management (DM) standardsxiv, as described in ‘Requirements for Certification of ECRIN Data Centres, with Explanation and Elaboration of Standards, Version 4.0’xv. Key to the programme’s effectiveness is the broad acceptance of the DM standards as well as a high-quality process to ensure adherence.

Given the significant changes in recent years for clinical trial data management (e.g. increasing use of cloud-based infrastructure and ‘software as a service’ (SaaS), new regulatory requirements for data integrity), the ECRIN DM standards underwent a comprehensive review in 2017. The new revised version 4.0 of the standards was published in 2018.

Programme Expansion

Recognising the certification model’s effectiveness, countries outside Europe and in particular in East and Southeast Asia (e.g. Singapore, Japan, South Korea, Taiwan) have expressed interest in adopting the programme. The first major steps for the ‘globalisation’ of data management centre certification were taken in 2017, with the translation of the DM standards (version 3.1) into Japanese, the training of Japanese auditors in February 2017 (at ECRIN’s Paris office), and the inclusion of Asian auditors (as observers) in three on-site audits of European data centres. In 2018, ECRIN continued to lay the groundwork for the expansion of the programme to Asia (and beyond), performing audits of two non-commercial Japanese data centres in the fall. The aims were to:

- Assess compliance of the data centres with ECRIN’s DM standards
- Oversee and approve the appointment of Japanese auditors
- Contribute to the training of auditors and preparation for the future implementation of a regional certification programme in Asia
A significant development in 2018 was the launch of a project which aims to:

• Develop a fit-for-purpose set of pharmacovigilance (PV) standards that provide interpretation of regulatory and good practice requirements in the context of academic central pharmacovigilance in Europe

• Identify the CTUs within ECRIN member or observers countries that are capable of running central PV services in compliance with the current EU requirements

For this purpose, ECRIN set up a working group composed of 19 experts, with at least one representative from each ECRIN member/observer country (individuals were selected by ECRIN’s Network Committee). The group met monthly and presented its work to the Network Committee on two occasions. The group is currently working on the development of a set of standards that will be used to evaluate pharmacovigilance centres’ compliance and ability to provide high-quality central pharmacovigilance tasks.

Pharmacovigilance Qualification and Compliance

A significant development in 2018 was the launch of a project which aims to:

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Benefits for Participants

The potential rewards for Data Management Centre Certification programme participants are numerous. Data centres can benefit from the sharing of the latest technical developments (maintenance of up-to-date standards reflecting state-of-the-art practice) and training on data management/IT ‘hot topics’ (e.g. data sharing, Clinical Data Interchange Standards Consortium - CDISC), clinical data management). Finally, auditors from CTUs involved in the certification programme receive advanced training on data management/IT, and thus may play a leading expert role in discussions on these topics in their respective countries.
ECRIN organises both internal and external training activities, presented below with updates from 2018.

**Staff Training**

**Summer School**

One of ECRIN’s main internal training events is the annual Summer School, targeted at European correspondents (EuCos) and the core team. In particular, the Summer School aims to provide training in areas related to the tasks performed by EuCos and the core team; to foster discussion on issues related to these tasks in a constructive environment; and to agree on potential courses of action to address potential problems.

In 2018, ECRIN held its Summer School in Toulouse, France from 3 to 5 September. Focus areas included stratification studies using multimodal data: challenges and practical solutions; GDPR; stratification studies: challenges for clinical research; and risk assessment.

A new feature of this year’s Summer School was a workshop on cross-cultural issues. In preparation for the session, participants were asked to complete a questionnaire, indicating any problems understanding or communicating with people from another culture; work methods which seem incompatible; or any frustrating, embarrassing or perplexing incident. The session was considered highly fruitful, and many solutions were proposed to facilitate collaboration between ECRIN’s diverse, multicultural and distributed team members, from email guidelines to team strengthening exercises.

**Other Internal Training Initiatives**

Also in 2018, ECRIN continued its part-time mentorship programme, which was introduced in 2017. Through the programme, one of the most experienced EuCos provides regular mentoring to the other EuCos, in addition to the support they receive from management staff in Paris.

**Training as a Service**

**RItrain**

In the context of its infrastructure development projects, ECRIN is involved in various training activities. For example, ECRIN hosted a knowledge/staff exchange as part of RItrain (Research Infrastructures Training Programme) from 22 to 23 November 2018 in Paris. The purpose of RItrain exchanges is to provide training to executive staff from European RIs in areas that are new to them, or in areas that they feel their RI needs to develop specific expertise in. ECRIN’s staff exchange focused on project management.

Participants included managerial staff from three European RIs: BBMRI (Biobanking and Biomolecular Resources Research Infrastructure)-Swedish Node, Instruct-ERIC (Integrated Structural Biology Infrastructure) hub, and ISBE (Infrastructure for Systems Biology-Europe).

Learn more: ritrain.eu/staff-exchanges

**MiRoR**

ECRIN also continued to be involved in training initiatives aiming to develop new methodologies for clinical research. In particular, ECRIN is a partner in the Marie Curie MiRoR (Methods in Research on Research) project. MiRoR supports a cohort of 15 PhD students working on various aspects of trial methodology with the objective of reducing waste in research. In 2018, ECRIN provided advice and feedback to four MiRoR PhD students on their research projects.

Learn more: http://miror-ejd.eu/
Communications

The optimisation of internal and external communications activities was a continued focus in 2018. Achievements included the creation of a new brochure, continued improvements to the website, and the increasing use of social media, with the number of Twitter followers reaching almost 500. A strategy document was initiated for 2019 with ambitious goals for website redesign, an external newsletter, increased scientific publication, an institutional video, webinars and more. In 2018 ECRIN also supported the communications activities of various infrastructure development projects, such as CORBEL and PedCRIN.

Scientific communication in particular was a central activity throughout 2018. ECRIN organised or co-organised various scientific meetings (e.g. ICTD 2018), and participated in European and international scientific conferences. In 2018, the Director General made 27 presentations at various conferences.

ECRIN contributed to six scientific publications (see below). ECRIN’s scientific publications are generally related to the trials that it supports, the projects it participates in or leads, its quality initiatives, and/or the activities of its national networks.

ECRIN Publications in 2018


Publications on ECRIN-Supported Trials in 2018


*An ECRIN publication that is also related to an ECRIN-related trial (see box next page).*
International Clinical Trials Day (ICTD) 2018: ‘Clinical Trials and Innovation’

ECRIN and its Hungarian national scientific partner, HECRIN, hosted the annual International Clinical Trials Day (ICTD) conference on 15 May 2018 at the Budapest Academy of Sciences. The theme was ‘Clinical Trials and Innovation’.

Celebrated every year on or around May 20th, ICTD is an opportunity for organisations, clinical research professionals, and the public to acknowledge the achievements that result from clinical research and to discuss various trial topics. ICTD was founded by ECRIN in 2005, and over the past 13 years, it has become an international event, with multiple celebrations around the world.

The theme of the 2018 edition, ‘Clinical Trials and Innovation’, was developed based on a use case and debated by a number of specialists in the field, with a focus on issues of regulation, financing, and innovation ecosystems (see speaker list and topics below). The aim was to increase awareness of ECRIN and HECRIN among Hungarian policymakers and the scientific community, as well as to address issues related to innovation and multinational clinical trials.

About 120-150 stakeholders (investigators, patient representatives, national authorities, health technology assessment specialists) involved in multinational clinical studies from across Europe and Hungary participated in the event.

ICTD 2018 Agenda

Welcome: Prof. György Kosztolányi Section of Medical Sciences - Hungarian Academy of Sciences (Budapest, Hungary)
Presentation: ‘The NOGO protein as a therapeutic target for spinal cord repair: a long journey from concept to clinical development’, Prof. Martin E. Schwab, director of Swiss Federal Institute of Technology (Zürich, Switzerland)
Presentation: ‘The regulatory context conditions for access to market’, Prof. Jorge Camarero Jimenez, head of oncology area, Spanish Agency for Medicines and Medical Devices (AEMPS) (Madrid, Spain)
Presentation: ‘Regulatory support: How can NIPN help stakeholders?’ Dr. Krisztián Fodor, directing manager of the Strategy, Methodology and Development Division and the Innovation Office of National Institute of Pharmacy and Nutrition (Budapest, Hungary)
Presentation: ‘Funding of value creating innovation RDI policy of Hungary’, Prof. József Pálinkás, president of National Research, Development and Innovation Office (Budapest, Hungary)
Presentation: ‘Funding innovation in European public funding, charity funding, public-private partnership, private investment, venture capital’, Dr. Pascale Augé, chairman of the Executive Management Board of Inserm Transfert (Paris, France)
Presentation: ‘The health innovation ecosystem in Hungary’, Prof. Gábor L. Kovács, head of oncology area, HECRIN and University of Pécs Szentágathoi Research Centre (Pécs, Hungary)
Discussion
Presentation: ‘The health innovation ecosystem in Europe: bioparks, translational research infrastructure (EATRIS)’, Dr. Toni Andreu, EATRIS scientific director (Amsterdam, The Netherlands)
Discussion
2018 was marked by the scaling up of activities, requiring changes in ECRIN’s internal organisation and staff competencies. New hires joined the organisation in the fall of 2018, and others were recruited to start early 2019.

*Note: the core team and European correspondent lists include individuals who started working for ECRIN in 2018, as well as those who left the organisation.

**Core Team**

Jacques Demotes  
Director General

Christine Kubiak  
Operations Director

Sabine Kläger  
Clinical Operations Manager

Gonzalo Calvo  
Medical Expert

Alicja Szofer-Araya  
Administrative and Finance Manager

Marta Bastucci  
Executive Assistant

Serena Battaglia  
Capacity Project Manager

Sabrina Gaber  
Communications Officer

Patricia Le Mouel  
Assistant

Jayne Maddock  
Administrative Assistant

Salma Malik  
Paediatric Project Manager

Mihaela Matei  
Legal and Regulatory Officer

Audrey Strader  
Clinical Operations Project Manager

Christine Toneatti  
Quality and Risk Manager

**European Correspondents**

Kateřina Nebeská  
Czech Republic

Lenka Součková  
Czech Republic

Amélie Michon  
France

Luc Wasungu  
France

Linda Stöhr  
Germany

Laura Vieweg  
Germany

Zita Tarjányi  
Hungary

Suzanne Bracken  
Ireland

Fiona Cregg  
Ireland

Elena Toschi  
Italy

Arianna Valerio  
Italy

Valentina Cabral Iversen  
Norway

Catarina Madeira  
Portugal

Simona Sonderlichová  
Slovakia

Stefan Toth  
Slovakia

Juan Ferrero-Cañero  
Spain

Eva Lopez-Guerrero  
Spain

Joaquin Sáez-Peñataro  
Spain

Caecilia Schmid  
Switzerland

**Experts and Consultants**

Vittorio Bertelé  
Scientific Board Secretariat

Chiara Gherardi  
Scientific Board Secretariat

Steve Canham  
Data Management Consultant

Christian Ohmann  
Data Management Expert

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15 In particular, these staff members were identified to fulfil roles in data management, clinical trial project management, and infrastructure project management. Changes were also made to the existing team organisation, with certain staff members taking on new or different roles as of early 2019.
National Scientific Partners

At a Glance

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*Observer country

“Hub” refers to the city where the national CTU network (i.e. national scientific partner) is headquartered. The hub generally provides central management services to the network of CTUs.

Czech Republic
Member since 1 Jan. 2018

**Scientific Partner:** CZE CRIN - Czech Clinical Research Infrastructure Network

CZE CRIN is a national research infrastructure network that facilitates academic clinical trials in the Czech Republic. It provides research, knowledge, methodological and service support for investigator-initiated clinical trials; it encourages national and international clinical research collaboration for the benefit of patients, habitants and healthcare. CZE CRIN is included in the Ministry of Education, Youth and Sports’ Roadmap for Large Research, Development and Innovation Infrastructures. Masaryk University was established as CZE CRIN’s national hub, coordinating the university module, with St. Anne’s University Hospital Brno as a partner coordinating the clinical module. The university module brings together clinical trial centres located in Czech universities. The clinical trials module, which currently includes seven CTUs within the university hospital, provides coordination and support services for investigator-initiated clinical trials, training activities, and methodological support.

**HIGHLIGHTS IN 2018**
- Became an ECRIN member country
- Sponsored 3 of its own academic clinical studies and supported 19 international academic clinical trials
- Manufactured investigated, advanced therapy medicinal product (ATMP) clean rooms under good manufacturing practice (GMP) conditions

**Website:** [www.czecrin.cz/czecrin-en](http://www.czecrin.cz/czecrin-en)
Hungary
Member since 5 Nov. 2014
Scientific Partner: HECRIN - Hungarian Clinical Research Infrastructure Network
HECRIN currently comprises 16 hospitals and medical institutes in Hungary. Its goal is to extend membership nationally and to establish clinical trial coordinating centres at member sites. The HECRIN central office is at the University of Pécs.

**HIGHLIGHTS IN 2018**
- Became involved in CONSCIOUS (Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students), an Erasmus+ project that aims to address skills gaps among European-level clinical trial professionals through curriculum development and e-learning. Coordinated by the University of Pécs, this project involves several ECRIN national networks (as direct beneficiaries): HECRIN, F-CRIN, PtCRIN, CZECRIN, CRDI
- Developed a joint cooperation agreement with AdWare Research Ltd. to increase the volume of investigator-initiated clinical trials, to support study-related data management tasks, and to provide analysis of study results through validated processes
- Co-organised ECRIN’s 2018 celebration of ICTD (see Communications section)
- Announced, in December 2018, HECRIN’s intention to organise ECRIN’s Summer School in Hungary in 2019.

Website: [www.hecrin.pte.hu/en](http://www.hecrin.pte.hu/en)

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Germany
Member since 29 Nov. 2013
Scientific Partner: KKSN - Netzwerk der Koordinierungszentren für Klinische Studien
KKS-Netzwerk (KKSN), the German network of coordinating centres for clinical trials, was established in 2005 and comprises 23 academic coordinating centres for clinical trials (as of December 2018). The KKSN headquarters are located in Berlin, next to the German ECRIN office. CTUs in KKSN provide full trial services ranging from consultancy on protocol design, budgeting and regulatory and ethical submissions to conducting trials, including project management, site management, data management, monitoring, (pharmaco-)vigilance and reporting for medical as well as for medicinal products. The KKSN structure enables close collaboration between study centres in multicentre trials, facilitating a high level of quality. Training is also a significant focus of the network. In addition, network members are involved in various national and international clinical research projects, and collaborate with diverse stakeholders.

**HIGHLIGHTS IN 2018**
- PD Dr. med. Sebastian Klammt, M.Sc. became head of the national coordination office
- Held workshops on risk-based quality management (RBQM) and personalised medicine
- Led a joint consultation process with industry, authorities and other stakeholders to improve conditions for clinical trials in Germany.

Website: [www.kks-netzwerk.de](http://www.kks-netzwerk.de)

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France
Member since 29 Nov. 2013
Scientific Partner: F-CRIN - French Clinical Research Infrastructure Network
F-CRIN, created in 2012, is the single contact point facilitating the participation of France in clinical studies. F-CRIN brings together the major academic and commercial stakeholders in clinical research in France, including clinical research and innovation departments in university hospitals, clinical investigation centres, and interregional groups for clinical research and innovation. F-CRIN enables multinational or multicentre, investigator-driven, clinical trials and early phase proof-of-concept studies. Clinical trial support is provided through F-CRIN by the EUCLID and PARTNERS platforms of professional services. F-CRIN also collaborates with networks specialised in specific diseases or areas of medicine (e.g. cardiology, nutrition, inflammatory disease, cardiorenal diseases, thrombosis, vaccinology, Parkinson’s disease, sepsis).

**HIGHLIGHTS IN 2018**
- Early January 2018, F-CRIN labelled 4 new investigational networks (for paediatrics, degenerative diseases of the retina, severe asthma, and multiple sclerosis). The F-CRIN community is thus growing and as of end 2018 had 17 components (12 networks, 4 platforms, 1 national coordination).
- ISO renewal audit: an audit confirmed the ISO 9001 certification of the F-CRIN management office (national hub) in Toulouse
- The H2020-funded ImmunAID (Immunome project consortium for Autoinflammatory Disorders) project started in May 2018. It will deliver a method for rapid and accurate diagnosis across the whole spectrum of systemic autoinflammatory diseases (SAIDs) in order to improve clinical management of patients. This European project brings together one of the F-CRIN investigational networks: IMMEDIATE, dedicated to auto-immune disease, F-CRIN and ECRIN.

Website: [www.fcrin.org](http://www.fcrin.org)
Ireland
Member since 20 Nov. 2018

Scientific Partner: HRB CRCI - Health Research Board Clinical Research Coordination Ireland
HRB CRCI is an independent integrated national clinical research network, providing centralised support in the conduct of multicentre clinical trials and investigations/studies (both commercial and academic) across Ireland ‘for the benefit of people’s health and the economy’. Operational since May 2015, it is funded by extramural people’s health and the economy’. Operational support in the conduct of multicentre clinical trials and investigations/studies (both commercial and academic) across Ireland ‘for the benefit of people’s health and the economy’. Operational

HIGHLIGHTS IN 2018
- Became an ECRIN member in November 2018, supported by the six medical schools in Ireland, and is hosted by Clinical Research Development Ireland (CRDI). The HRB CRCI central office provides overarching support and expertise, through a range of services and activities to academia and industry. CRDI provides corporate support services to the central office. The partner university clinical research facilities/centres (CRFs/CRCs)22 provide the infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight programmes that are critical for the successful conduct of world-class, patient-focused research.

HIGHLIGHTS IN 2018
- Became an ECRIN member in November 2018, which includes hosting the EuCo position
- The HRB CRCI network expanded in 2018 to include the University of Limerick and Our Lady’s Children’s Hospital, Crumlin
- HRB CRCI completed the first cycle of the mutual recognition scheme of the CRFs/CRCs QMS

Website: www.hrb-crci.ie

Italy
Member since 29 Nov. 2013

Scientific Partner: ISS - Istituto Superiore di Sanità / ItaCRIN
- Italian Clinical Research Infrastructure Network
ItaCRIN is the national clinical research infrastructure in Italy. ItaCRIN currently comprises nine participants capable of providing services for clinical research. The network includes academic CTUs and CTUs with IRCCS ‘Istituto di Ricerca e Cura a Carattere Scientifico’23 accreditation, as well as clinical research organisations (CROs) dedicated to independent clinical studies. The national hub of ItaCRIN is located at the Istituto Superiore di Sanità (ISS) in Rome. The main purpose of ItaCRIN is to promote, through international networking, excellent non-profit clinical research focused on identifying advanced therapeutic strategies for the benefit of public health.

HIGHLIGHTS IN 2018
- The ItaCRIN team grew, adding two support people and one IT expert to the existing staff (national coordinator, EuCo).
- The new staff members are part of the Research Coordination and Support Service (CoRi) and the National Centre of Drug Research and Evaluation (Farvac). The ItaCRIN team works in close collaboration with the team from the EATRIS Italian node (A_Iatris) and the scientific-technical secretariat of BBMRI.it, which are located in dedicated offices in the same building and jointly supervised by Dr. Luca Mignetti, director of CoRi.
- A new ItaCRIN website was created (www.itaclin.it) and its final version is expected to launch by mid-2019.
- To enlarge the ItaCRIN network, contacts were established with the major Italian network of oncological hospitals (Alliance Against Cancer, ACC).

Website: www.itaclin.it

Norway
Member since 18 May 2016

Scientific Partner: NorCRIN - Norwegian Clinical Research Infrastructure.
NorCRIN’s aim is to facilitate clinical research by supporting the many complex elements of this type of research, such as study design, the application process, trial conduct, and GCP reporting. The main objective is to strengthen and simplify collaboration within all categories of clinical research in Norway. The Ministry of Health and Care Services in Norway initiated the founding of NorCRIN, and Trondheim University Hospital (St. Olav’s Hospital) is responsible for coordinating and operating the network.

HIGHLIGHTS IN 2018
- Applied for Norwegian Research Council funding to remain an ECRIN member beyond 2020
- Conducted a user survey24
- Redesigned the NorCRIN website (with responsive design for mobile phone use)
- Became involved in three ECRIN-led working groups (quality, lead CTU, PV)
- Decided on new tasks for 2019-2020: establishment of work packages for clinical research infrastructure development, development of e-learning courses on GCP
- Formalised collaboration with CRIGH and the Norwegian Primary Care Research Network (PraksisNett)
- Established two new work packages (involving all NorCRIN partners): one on statistics and another on the certification of study nurses
- As part of existing work packages, the network also established procedures for handling PV and developed ‘eBudget’, a model for use in clinical trials

Website: www.norcrin.no/in-english

Portugal
Member since 29 Nov. 2013

Scientific Partner: PtCRIN - Portuguese Clinical Research Infrastructure Network.
PtCRIN is the national research infrastructure for clinical research in Portugal. PtCRIN is composed of 14 members which represent the leading Portuguese clinical research institutions, including hospitals, medical centres, universities and a research organisation. PtCRIN is currently working on the development of a network of academic CROs and clinical sites. PtCRIN will position Portugal strategically in the rapidly evolving field of clinical research, giving Portuguese investigators an opportunity to influence the development of ethical guidelines, best practices, and new standards. In addition, European researchers will have access to Portugal as a clinical research venue.

HIGHLIGHTS IN 2018
- Contributed to the preparation and launching of a Clinical Investigator Certificate (CLIC) Level II course
- Participated in 10 training courses and meetings, making presentations about clinical research in Portugal
- Continued to participate in six ECRIN-supported multinational clinical trials
- Co-organised the first annual meeting of the TESA II project in Lisbon in September
- Was involved in four ECRIN infrastructure development projects: TESA II, TRANSVAC2 II, CONSCIOUS, CRIGH
- Contributed to multiple European funding applications for multinational clinical trials
- Expanded the EuCo team, with the addition of Joana Batuca, bringing the number of Portuguese EuCos to two25
- Celebrated 5 years as an ECRIN member country

Website: www.pctrin.pt

22 HRB CRCI’s partner CRFs/CRCs include: HRB CRF Cork at University College Cork and Mercy University Hospital; HRB CRF Galway at University Hospital Galway; Royal College of Surgeons Ireland CRC at Beaumont Hospital; University College Dublin CRCs at Mater Misericordiae University Hospital and St. Vincent’s University Hospital, Welcome Trust – HRB CRF at St. James’s Hospital; HR-CSU Health Research Institute Clinical Research Support Unit at University Hospital Limerick, Co Limerick; NCLRC National Children’s Research Centre at Our Lady’s Children’s Hospital, Crumlin, Dublin 12.

23 IRCCS status is awarded to biomedical institutions of relevant national interest, which aim clinical assistance in strong relation to research activities. Their mission is the continuous upgrade of healthcare. The IRCCS title is granted by Italian Department of Health to a very limited number of institutions.

24 A user survey was conducted in September 2018, with a total of 149 respondents. Users indicated their involvement in academic vs. industrial studies (75% and 46%, respectively), means by which they became aware of NorCRIN, and satisfaction with NorCRIN services (+72% of users indicating they were satisfied or very satisfied).

Slovakia
Observer since 1 July 2018

**Scientific Partner:** SLOVACRIN - Slovak Clinical Research Infrastructure Network

SLOVACRIN is a national research infrastructure network connecting hospitals, universities and scientific institutions involved in academic clinical research. It is coordinated by the Faculty of Medicine of the Pavol Jozef Šafárik University in Košice. The General Director of SLOVACRIN and the Dean of the Faculty of Medicine is Prof. Daniel Pella. SLOVACRIN supports the preparation and implementation of academic clinical studies in Slovakia, including international studies. The aim is to increase the number and quality of academically-initiated clinical trials in Slovakia, using the available capacity and expertise to ensure compliance with regulatory, legislative and ethical requirements related to clinical research.

**HIGHLIGHTS IN 2018**
- Prof. Pella presented SLOVACRIN’s vision and its coordination abilities at the ECRIN AoM Meeting in Budapest (May 2018)
- Ministry of Health (MoH) applied for Slovakia to be an ECRIN observer, and Prof. Pella was nominated for the AoM (June 2018)
- Became an ECRIN observer (following AoM approval) (July 2018)
- SLOVACRIN kick-off meeting held at Slovak MoH (11 Sept. 2018)
- Initial training for EuCos with the ECRIN core team in Paris (Oct. 2018)
- SLOVACRIN became a participant in the EOSC-Life project (Nov. 2018)

Website: [www.upjs.sk/en/faculty-of-medicine](http://www.upjs.sk/en/faculty-of-medicine)

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Spain
Member since 29 Nov. 2013

**Scientific Partner:** SCReN - Spanish Clinical Research Network

SCReN is a network of Spanish CTUs based in clinical centres of the Spanish National Health Service. There are currently 30 CTUs in the network spanning 12 Spanish autonomous communities. The SCReN coordinators are based in the Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC) in Madrid. Three working groups specialise in regulation and monitoring; methodological assessment, data management and statistics; and pharmacovigilance.

SCReN aims to foster excellence and quality in clinical research through networking, international cooperation, and support to clinical research projects, translating them into benefits for the Spanish National Health Service. SCReN also works on education and training of clinical research professionals.

**HIGHLIGHTS IN 2018**
- First year working under the new multi-year funding (2018-2020) provided by the National Institute of Health ‘Instituto de Salud Carlos III’ (total budget: €7,698,490.00).
- Affiliation of three new CTUs to the network, growing to 31 units
- 12 new studies incorporated into the SCReN clinical plan, which is currently composed of: 6 studies in the early design phase; 11 in start-up; 44 with active enrolment (630 sites and more than 3,000 patients enrolled); 11 in the follow-up phase; 2 with close-out activities; and a total of 28 trials completed

Website: [www.scren.es](http://www.scren.es)

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Switzerland
Observer since 18 December 2015

**Scientific Partner:** SCTO - Swiss Clinical Trial Organisation

SCTO is the central cooperation platform for patient-oriented clinical research in Switzerland. Its primary objective is to position Swiss clinical research as attractive and competitive internationally with respect to innovation and quality. The SCTO intends to achieve this mandate by: promoting a high-quality and nationally harmonised study culture; supporting the creation of a national network; boosting integration of national clinical research into international networks; and building bridges between academia, industry and public authorities. The SCTO advocates for favourable framework conditions in the field of clinical research, and coordinates and acts as an intermediary in multicentre studies. The SCTO was established in 2009 and since 2013 it has acted as an independent organisation, funded by the Swiss National Science Foundation (SNSF) and State Secretariat for Education, Research and Innovation (SERI).

**HIGHLIGHTS IN 2018**
- Established thematic platforms that aim to be the first point of contact for questions regarding clinical research (focus areas: auditing, statistics, data management, education, monitoring, project management, regulatory affairs, and safety)
- Switzerland organised the tri-national DACH Symposium on clinical research, hosted by University Zurich from 11-12 June 2018, attracting more than 550 participants
- A member of the SCTO network, University Hospital Basel, published a first-of-its-kind framework (called ‘INQUIRE’) to optimise patient-oriented clinical research internationally
- The framework brings together the best of thinking from 7 stakeholder groups across 16 countries which took part in a rigorous Delphi process to distil their combined expertise into distinct steps ([https://drf.unibas.ch/de/inquire](https://drf.unibas.ch/de/inquire))

Website: [www.scto.ch/en](http://www.scto.ch/en)
Assembly of Members
ECRIN is governed by an Assembly of Members (AoM), which is composed of a representative from the government of each member or observer country. The AoM is chaired by Rafael de Andrés Medina of Carlos III Health Institute (Instituto de Salud Carlos III, ISCIII), Spain, and the vice chair is Maria Ferrantini (Italy).

Members
- Marta Abrantes (Portugal)
- Renáta Chudackova (Czech Republic)
- Alexander Grundmann (Germany)
- Eric Guittet (France)
- Annette Magnin (Switzerland)
- Øyvind Melien (Norway)
- Daniel Pella (Slovakia)
- Csaba Vadadi-Fülöp (Hungary)
- Oonagh Ward (Ireland)

Additional Organisational Bodies
Network Committee
The Network Committee represents the national scientific partners and provides advice to the AoM and Director General. It is composed of one senior delegate from each national scientific partner of member and observer countries. In 2018, the Network Committee was chaired by Christian Ohmann (Germany). The vice chair was Annette Magnin (Switzerland) and members included Ola Dale (Norway), Regina Demlova (Czech Republic), Gábor Kovács (Hungary), Emilia Monterio (Portugal), Lucia Palmisano (Italy), Daniel Pella (Slovakia), Antonio Portoles (Spain), Olivier Rascol (France), Fabian Tay (Switzerland) and Heiko Von Der Leyen (Germany).

Governance Meetings in 2018

<table>
<thead>
<tr>
<th>BODY</th>
<th>DATES</th>
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<tbody>
<tr>
<td>Assembly of Members</td>
<td>15 May 2018</td>
</tr>
<tr>
<td></td>
<td>29 June 2018 (teleconference)</td>
</tr>
<tr>
<td></td>
<td>11 December 2018</td>
</tr>
<tr>
<td>Network Committee</td>
<td>14 November 2018</td>
</tr>
<tr>
<td></td>
<td>14 May 2018</td>
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</table>

Steering Committee
ECRIN’s Steering Committee oversees activities and provides advice on budget, work plan and scientific/technical matters. It is composed of the Chair and Vice Chair of the AoM, the Chair and Vice Chair of the Network Committee, as well as the Director General.

Advisory Board
The ECRIN Advisory Board is composed of individuals representing diverse areas related to clinical research, both in Europe and internationally. Members provide input and recommendations to the AoM on all matters related to the activities of the infrastructure and its further development. As of 2018, members include: Paul Avillach (Harvard Medical School), Patrick Bassuyt (University of Amsterdam), Frank Hulstaert (Belgian Health Care Knowledge Centre, KCE), Kaisa Immonen (European Patient’s Forum), Michal Koščík (Masaryk University), Shaun Treweek (University of Aberdeen), Effy Vayena (University of Zurich), and Maria Blettner (Johannes Gutenberg University Mainz).

\(^{21}\) In particular, the Advisory Board may provide input/recommendations on ECRIN’s strategy and future strategic development; scientific and technical development; ethical and personal data protection issues raised by ECRIN’s activities; access to data and transparency policies; and methodological recommendations.
## Financial Report for 2018

<table>
<thead>
<tr>
<th>Income</th>
<th>Amount (€)</th>
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<tr>
<td>Membership Core contributions</td>
<td>1 255 000</td>
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<tr>
<td>Membership Local contributions</td>
<td>850 000</td>
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<tr>
<td>Research projects</td>
<td>1 216 076</td>
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<tr>
<td>Other income</td>
<td>43 468</td>
</tr>
<tr>
<td><strong>Total Income for 2018</strong></td>
<td><strong>3 376 667</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Expenditures</th>
<th>Amount (€)</th>
</tr>
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<tbody>
<tr>
<td>Salaries, social expenses and taxes</td>
<td>1 157 871</td>
</tr>
<tr>
<td>Services</td>
<td>809 620</td>
</tr>
<tr>
<td>Travel and meetings</td>
<td>225 067</td>
</tr>
<tr>
<td>Rent and insurance</td>
<td>171 914</td>
</tr>
<tr>
<td>Scientific Board</td>
<td>105 800</td>
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<tr>
<td>Fees for consultants</td>
<td>200 136</td>
</tr>
<tr>
<td>Other expenses</td>
<td>83 830</td>
</tr>
<tr>
<td>Local contribution provided in-kind</td>
<td>550 000</td>
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<tr>
<td><strong>Total Expenditure for 2018</strong></td>
<td><strong>3 304 238</strong></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Net Results</th>
<th>Amount (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net Results for 2018</strong></td>
<td><strong>72 429</strong></td>
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</table>

## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ACC</td>
<td>Alliance Against Cancer (Italy)</td>
</tr>
<tr>
<td>AoM</td>
<td>Assembly of Members</td>
</tr>
<tr>
<td>ATMP</td>
<td>Advanced therapy medicinal product</td>
</tr>
<tr>
<td>BBMRI</td>
<td>Biobanking and Biomolecular Resources Research Infrastructure</td>
</tr>
<tr>
<td>BMS RIs</td>
<td>Biological and Medical Sciences Research Infrastructures</td>
</tr>
<tr>
<td>c4c</td>
<td>connect4children</td>
</tr>
<tr>
<td>CAPA</td>
<td>Corrective Action and Prevention Action</td>
</tr>
<tr>
<td>CDISC</td>
<td>Clinical Data Interchange Standards Consortium</td>
</tr>
<tr>
<td>CLIC</td>
<td>Clinical Investigator Certificate</td>
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<tr>
<td>CONSCIOUS</td>
<td>Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students</td>
</tr>
<tr>
<td>CORBEL</td>
<td>Coordinated Research Infrastructures Building Enduring</td>
</tr>
<tr>
<td>CoRi</td>
<td>Coordination and Support Service (Italy)</td>
</tr>
<tr>
<td>CRC</td>
<td>Clinical research centre</td>
</tr>
<tr>
<td>CRDI</td>
<td>Clinical Research Development Ireland</td>
</tr>
<tr>
<td>CRFs/CRCs</td>
<td>Clinical research facilities/Clinical research centres</td>
</tr>
<tr>
<td>CRIGH</td>
<td>Clinical Research Initiative for Global Health</td>
</tr>
<tr>
<td>CRO</td>
<td>Clinical research organisation</td>
</tr>
<tr>
<td>CTU</td>
<td>Clinical trial unit</td>
</tr>
<tr>
<td>CZECRIN</td>
<td>Czech Clinical Research Infrastructure Network</td>
</tr>
<tr>
<td>DM</td>
<td>Data management</td>
</tr>
<tr>
<td>EATRIS</td>
<td>European Advanced Translational Research Infrastructure in Medicine</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>EBRA</td>
<td>European Brain Research Area</td>
</tr>
<tr>
<td>ECRAID-Plan</td>
<td>European Clinical Research Alliance on Infectious Diseases Business Plan</td>
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<tr>
<td>ECRIN</td>
<td>European Clinical Research Infrastructure Network</td>
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<tr>
<td>ECRIN-IA</td>
<td>ECRIN Integrating Activity</td>
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<tr>
<td>EI</td>
<td>Enterprise Ireland</td>
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<tr>
<td>EJP RD</td>
<td>European Joint Programme on Rare Diseases</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<tr>
<td>EOSC</td>
<td>European Open Science Cloud</td>
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<tr>
<td>EOSC-hub</td>
<td>European Open Science Cloud hub</td>
</tr>
<tr>
<td>EOSC-Life</td>
<td>European Open Science Cloud Life project (Providing an open collaborative space for digital biology in Europe)</td>
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<tr>
<td>EOSCpilot</td>
<td>European Open Science Cloud pilot</td>
</tr>
<tr>
<td>EPTRI</td>
<td>European Paediatric Translational Research Infrastructure</td>
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<tr>
<td>ERIC</td>
<td>European Research Infrastructure Consortium</td>
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<td>ERIC Forum</td>
<td>ERI Forum Implementation project</td>
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<tr>
<td>ESFRI</td>
<td>European Strategy Forum on Research Infrastructures</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>EuCo</td>
<td>European Correspondent</td>
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<tr>
<td>EuLac-PerMed</td>
<td>Widening EU-CELAC policy and research cooperation in Personalised Medicine</td>
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<tr>
<td>FARVA</td>
<td>National Centre of Drug Research and Evaluation (Italy)</td>
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<tr>
<td>F-CRIN</td>
<td>French Clinical Research Infrastructure Network</td>
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<tr>
<td>FDA</td>
<td>(U.S.) Food and Drug Administration</td>
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<td>FP6</td>
<td>Sixth Framework Programme</td>
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<tr>
<td>FP7</td>
<td>Seventh Framework Programme</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>GDPR</td>
<td>General Data Protection Regulation</td>
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<tr>
<td>GMP</td>
<td>Good manufacturing practice</td>
</tr>
<tr>
<td>GSF</td>
<td>(OECD) Global Science Forum initiative</td>
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<tr>
<td>GDPR</td>
<td>General Data Protection Regulation</td>
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<td>H2020</td>
<td>Horizon 2020</td>
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<tr>
<td>HECRIN</td>
<td>Hungarian Clinical Research Infrastructure Network</td>
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<td>HRB CRCI</td>
<td>Health Research Board Clinical Research Coordination</td>
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<td>HRB</td>
<td>Health Research Board (Ireland)</td>
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<tr>
<td>ICB</td>
<td>(ECRIN) Independent Certification Board</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference on Harmonisation</td>
</tr>
<tr>
<td>ICTD</td>
<td>International Clinical Trials Day</td>
</tr>
<tr>
<td>IDIiSSC</td>
<td>Instituto de Investigación Sanitaria del Hospital Clínico San Carlo</td>
</tr>
<tr>
<td>IMI</td>
<td>Innovative Medicines Initiative</td>
</tr>
<tr>
<td>Instruct</td>
<td>Integrated Structural Biology Infrastructure</td>
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<tr>
<td>IRCSS</td>
<td>Istituto di Ricovery e Cura a Carattere Scientifico</td>
</tr>
<tr>
<td>ISBE</td>
<td>Infrastructure for Systems Biology-Europe</td>
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<tr>
<td>ISCIII</td>
<td>Carlos III Health Institute (Instituto de Salud Carlos III)</td>
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<tr>
<td>ISS</td>
<td>Istituto Superiore di Sanita</td>
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<tr>
<td>ItaCRIN</td>
<td>Italian Clinical Research Infrastructure Network</td>
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<tr>
<td>KKS Dresden</td>
<td>Coordination Centre for Clinical Trials Dresden</td>
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<tr>
<td>KKS Heidelberg</td>
<td>Coordination Centre for Clinical Trials (KKS) Heidelberg</td>
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<tr>
<td>KKSN</td>
<td>Netzwerk der Koordinierungscentren für Klinische Studien</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>KPI</td>
<td>Key performance indicator</td>
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<tr>
<td>MiRoR</td>
<td>Methods in Research on Research (project)</td>
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<tr>
<td>MIUF</td>
<td>Medical Infrastructure/ Users Forum</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MoU</td>
<td>Memorandum of understanding</td>
</tr>
<tr>
<td>NIH</td>
<td>(U.S.) National Institutes of Health</td>
</tr>
<tr>
<td>NorCRIN</td>
<td>Norwegian Clinical Research Infrastructure</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OPBG</td>
<td>Ospedale Pediatrico Bambino Gesu</td>
</tr>
<tr>
<td>PedCRIN</td>
<td>Paediatric Clinical Research Infrastructure Network</td>
</tr>
<tr>
<td>PTCRIN</td>
<td>Portuguese Clinical Research Infrastructure Network</td>
</tr>
<tr>
<td>PV</td>
<td>Pharmacovigilance</td>
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<tr>
<td>QMS</td>
<td>Quality management system</td>
</tr>
<tr>
<td>RBQM</td>
<td>Risk-based quality management</td>
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<tr>
<td>RI</td>
<td>Research infrastructure</td>
</tr>
<tr>
<td>RItrain</td>
<td>Research Infrastructures Training Programme (project)</td>
</tr>
<tr>
<td>RI-VIS</td>
<td>Expanding research infrastructure visibility to strengthen strategic partnerships</td>
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<tr>
<td>SaaS</td>
<td>Software as a service</td>
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<tr>
<td>SAID</td>
<td>Systemic autoinflammatory disease</td>
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<tr>
<td>SCReN</td>
<td>Spanish Clinical Research Network</td>
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<tr>
<td>SCTO</td>
<td>Swiss Clinical Trial Organisation</td>
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<td>SERI</td>
<td>State Secretariat for Education, Research and Innovation (Switzerland)</td>
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<td>SLOVACRIN</td>
<td>Slovak Clinical Research Infrastructure Network</td>
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<td>SNSF</td>
<td>Swiss National Science Foundation</td>
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<td>SYNCHROS</td>
<td>SYnergies for Cohorts in Health: integrating the Role of all Stakeholders</td>
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<td>TBMEd</td>
<td>A testing bed for the development of high-risk medical devices</td>
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<td>TESAIi</td>
<td>Trials of Excellence for Southern Africa II</td>
</tr>
<tr>
<td>TRANSVAC</td>
<td>European Network of Vaccine Research and Development</td>
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<tr>
<td>TRANSVAC2</td>
<td>European Network of Vaccine Research and Development (project)</td>
</tr>
<tr>
<td>XDC</td>
<td>eXtreme DataCloud</td>
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Project Funding and Other References

ECRIN-IA received funding from the European Union’s (EU’s) Seventh Framework Programme for Capacities (FP7) - Research Infrastructures under grant agreement (GA) number (no.) 284395.

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**ECRAID-Plan is funded by the European Commission under GA no. 825715.**

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**TB-Med is funded by H2020 under GA no. 825884.**

**SYNCHROS is funded by H2020 under GA no. 825884.**

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